

Application No.: 10/722,367
Filing Date: November 25, 2003

REMARKS

The following remarks are responsive to the Office Action dated March 26, 2008 (hereinafter, "Office Action"). As discussed below, Claims 24-27 are canceled by this amendment, and Claims 1-15 remain pending in the present application.

Claim Cancellations:

While Applicants respectfully disagree with the Examiner's rejections with regard to Claims 24-27, to advance prosecution, Applicants have canceled Claims 24-27. Applicants are not acquiescing to the rejections of these claims and reserve the right to pursue claims at least as broad as those that were canceled in a related application. Applicants respectfully request the Examiner to reconsider the above-captioned application in view of the foregoing claim cancellations and the following comments.

Claim Rejections – 35 U.S.C. 103:

Applicants submit that the Office Action fails to satisfy the required burden in establishing an obviousness rejection based, in part, on the requirements set forth in the Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in view of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*

For example, as will be described below, the proposed combinations involves several modifications and changes to the prior art. However, the Office Action fails to articulate specific rationales for the proposed combinations and modifications of the references, while also ignoring the whole teachings of the prior art references.

As discussed more fully below, there are significant differences between the cited references and the claimed devices of Claims 1-9 and 10-15 that do not appear to have been considered in reaching the conclusions set forth in the Office Action. Some of the distinctions between the cited references in the invention set forth in Claims 1-15, without limitation, are listed below, along with a discussion of the significance of these distinctions.

- U.S. Patent No. 5,769,885 ("Quiachon") discloses/suggests a deployment system for a balloon expandable prosthesis (i.e., not a self-expandable prosthesis), while Claims 1-15 are directed to deployment systems for self-expandable bifurcated prostheses.

- U.S. Patent No. 5,720,735 (“Dorros”) discloses/suggests sleeves that are axially withdrawn, while Claims 1-15 are directed to peelable covers. The longitudinal cuts in Dorros’ sleeves merely perform the function of permitting the sleeves to be axially withdrawn without interference from opposing bifurcated branches.
- In Dorros, the stents are positioned within the endovascular catheter in the opposite orientation as compared to the graft of Claims 1-15 and the deployment system disclosed in Quiachon.
- U.S. Patent No. 5,647,857 (“Anderson”) does not disclose a bifurcated prosthesis, distinguishing it from the bifurcated graft/prosthesis of Claims 1-15.

Rejection of Claims 1-9 under 35 U.S.C. 103(a):

Claims 1-9 stand rejected under 35 U.S.C. as being unpatentable over Quiachon in view of Dorros and Anderson.

For the reasons set forth below, Applicants submit that one skilled in the art would not modify Quiachon’s intraluminal grafting system as proposed by the Examiner in the Office action. In short, among other reasons, there is no advantage to combine the sleeves disclosed in Dorros with the balloon expandable stent in Quiachon. The balloon expandable stent in Quiachon gains no advantage from the inclusion of the additional restraints set forth in Dorros. Accordingly, Applicants submit that there would be no motivation to do so.

In particular, with regard to Claim 1, for the reasons stated herein, one skilled in the art would not be motivated by Dorros, or his or her own knowledge, to modify Quiachon to provide a bifurcation graft deployment system comprising, inter alia, and outer sheath *and* individual restraints on each of the graft portions, as set forth in Claim 1. Contrary to the balloon expandable graft in Quiachon (*see* Quiachon, col. 9, line 4-6), Claim 1, as amended, recites a self-expandable graft and a graft restraint for restraining the respective portions of the self expandable graft.

Dorros does relate to self-expandable stents. The embodiment disclosed in Dorros that comprises the two coaxial sleeves 60 and 62 cited in the Office Action also includes “self-expanding” stents 64 and 66 that, “when the surrounding sleeves 60 and 62 are withdrawn, [] expand radially outward to engage the surrounding vessel wall and dilate the vessel lumen.” (*see*

Dorros, col. 6, lines 10-18). However, because the graft of Quiachon is balloon expandable and, hence, not self-expandable, Applicants submit that one skilled in the relevant art (endoluminal vascular treatment) would not be motivated to combine the sleeves 60, 62 with the system of Quiachon to produce a device as in Claim 1 with any reasonable expectation of success.

Furthermore, Applicants submit that Quiachon does not disclose or suggest a distal tip coupled to the inner core. As shown in Figure 1 of Quiachon, the distal capsule assembly 90 is not a tip, since the distal extremity 80 of the balloon catheter shaft protrudes further to the distal end of the catheter than the distal capsule assembly 90.

Applicants also submit that Dorros does not disclose peelable covers, contrary to the conclusion set forth in the Office Action. Dorros discloses/suggests sleeves 60, 62 that Applicants submit can only be axially withdrawn, as indicated by the arrows 84, 86 in Figures 8-11 (*see* Dorros, col. 6, lines 41-51). The longitudinal cuts 70 in Dorros' sleeves merely perform the function of permitting the sleeves 60, 62 to be axially withdrawn without interference from the opposing bifurcated branch and sleeve (*see* Dorros, col. 6, lines 46-50). Dorros never discloses or suggests that the sleeves 60, 62 are peelable or can be peeled to release the stents.

Further, the stents 64, 66 of Dorros are positioned within the endovascular catheter in the opposite orientation as compared to the graft of Claim 1 and in the opposite orientation as compared to the stents disclosed in Quiachon. The stents 64, 66 of Dorros are loaded so as to be positioned nearer to the distal end of the bifurcated catheter. In contrast, in Claim 1, the graft is loaded in the opposite orientation, i.e., such that the main vessel portion (or distal end of the bifurcated prosthesis, as in Claim 10) is positioned nearer to the distal end of the catheter body than either the first branch vessel portion or the second branch vessel portion.

The opposite orientation of the stents in Dorros is significant because the stents, if arranged as set forth in Dorros, would not be positionable in a bifurcated vessel using the deployment system of Claim 1 because the branched portions would be facing the opposite direction relative to the patient's bifurcated vessel. Further, importantly, the arrangement in Dorros is significantly different than the arrangement disclosed in Quiachon for the same reason – i.e., because the stents, if arranged as set forth in Dorros, would not be positionable in the bifurcated vessel by the delivery system described in Quiachon because the branched portions would also be facing the opposite direction as compared to the patient's bifurcated vessel.

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Additionally, as a consequence of the opposite orientation of the stents relative to the delivery system disclosed in Dorros, if the delivery system were modified to include Dorros' sleeves 60, 62, as the Office Action suggests, the sleeves 60, 62 would not be removable by the system disclosed in Quiachon, thereby frustrating the purpose of the Quiachon delivery system. In Dorros, the sleeves 60, 62, with the longitudinal cut 70, are configured to be removed axially in a direction away from the bifurcation and toward the main body portion of the graft. This can be achieved in Dorros due to the orientation of Dorros' bifurcated graft relative to Dorros' delivery system, which is the opposite orientation as compared to that of Quiachon and Claims 1-15, as discussed above. Because the delivery system in Quiachon is positioned within the bifurcated vessel in the opposite orientation as compared to Dorros, the sleeves 60, 62, as configured in Dorros, would not be removable by Quiachon's delivery system. In particular, the sleeves 60, 62 of Dorros, which are configured to be removed only in a direction away from the bifurcation and toward the main body portion of the graft, would have to be removed in a direction pointing away from the distal end of the catheter in Quiachon, which Applicants submit the Quiachon catheter is not capable of doing, at least not without significant modification. For these reasons, one of ordinary skill in the art would not be motivated to modify the delivery system disclosed in Quiachon with the sleeves 60, 62 disclosed in Dorros.

One of ordinary skill in the art cannot be reasonably expected to completely rearrange the elements of the cited art as suggested by the Office Action to achieve the device as set forth in Claim 1. Such a rearrangement is a significant modification of the cited references, well beyond the teachings of the cited references, with no obvious or predictable advantage.

Applicants further submit that Claims 2-8 define patentable distinctions over the cited references, not only for the reasons stated above with respect to Claim 1, but also on their own merit. In particular, regarding Claim 2, Anderson discloses the use of a release element to remove a sheath 10 that "holds the stent-and-graft combination tightly onto the catheter." (*see* Anderson, col. 4, lines 57-58). While the prosthesis in Anderson may be balloon expandable, the sheath 10 is the only sheath or cover disclosed in Anderson that covers the graft and holds it in position relative to the catheter, which is seemingly the main reason why the balloon expandable graft of Anderson requires the sheath 10. The grafting system of Quiachon already has a main

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sheath 160 that is axially movable relative to the graft, so there would be no motivation to add another sheath or the strand 30 of Anderson to the Quiachon system.

For the foregoing reasons, Applicants respectfully request the Examiner to also withdraw the rejection of Claims 1-9 and to pass these claims to allowance.

Rejection of Claims 10-15 under 35 U.S.C. 103(a):

Claims 10-15 stand rejected under 35 U.S.C. as being unpatentable over Quiachon in view of Dorros. As discussed in greater detail above, Applicants respectfully submit that Examiner's rejection is improper because, inter alia, the Office Action fails to set forth the level of ordinary skill in the pertinent art, who qualifies as one of ordinary skill in the field, or any specific rationales for the proposed combinations of references.

Moreover, Applicants submit that one skilled in the art would not look to Dorros to modify Quiachon's intraluminal grafting system as proposed by the Examiner in the Office action.

In particular, with regard to Claim 10, for the reasons stated herein, one skilled in the art would not be motivated by Dorros, or his or her own knowledge, to modify Quiachon to provide a deployment system for deploying a bifurcated prosthesis comprising, inter alia, a self expanding bifurcated prosthesis having a main body section with proximal and distal ends and first and second branch sections at the proximal end of the main body section, wherein the main body section is held in a radially compressed state by a first peelable cover, the first branch section is held in a radially compressed state within a first tubular cover, and the second branch section is held in a radially compressed state within a second tubular cover.

Because the graft of Quiachon is balloon expandable and, hence, not self-expandable, Applicants submit that one skilled in the relevant art (endoluminal vascular treatment) would not be motivated to utilize the teachings of Dorros to modify Quiachon to produce a device as claimed in Claim 10 with reasonable expectation of success. On this basis, Applicants respectfully request the Examiner to reconsider and allow all of the above-listed claims.

Applicants further submit that Claims 11-15 define patentable distinctions over the cited references, not only for the reasons stated above with respect to Claim 10, but also on their own

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merit. Accordingly, Applicants respectfully request the Examiner to also withdraw the rejection of Claims 10-15 and to pass these claims to allowance.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicants wish to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
11/417,651 ENDOLOG.007C4	ENDOLUMINAL VASCULAR PROSTHESIS	05-03-2006
11/623,679 ENDOLOG.007C5	ENDOLUMINAL VASCULAR PROSTHESIS	01-16-2007
10/119,525 ENDOLOG.014C1	SELF EXPANDED BIFURCATED ENDOVASCULAR PROSTHESIS	04-08-2002
11/417,883 ENDOLOG.014C2	SELF EXPANDED BIFURCATED ENDOVASCULAR PROSTHESIS	05-03-2006
10/706,660 ENDOLOG.028C2	DUAL WIRE PLACEMENT CATHETER	11-12-2003
10/820,455 ENDOLOG.054A	ENDOLUMENAL VASCULAR PROSTHESIS WITH NEOINTIMA INHIBITING POLYMERIC SLEEVE	04-08-2004
11/104,303 ENDOLOG.056A	METHOD AND APPARATUS FOR DECOMPRESSING ANEURYSMS	04-12-2005
11/580,201 ENDOLOG.056CP1	METHOD AND APPARATUS FOR DECOMPRESSING ANEURYSMS	10-12-2006
11/522,292 ENDOLOG.067A	MULTI-SEGMENTED GRAFT DEPLOYMENT SYSTEM	09-15-2006
11/623,022 ENDOLOG.075A	DUAL CONCENTRIC GUIDEWIRE AND METHODS OF BIFURCATED GRAFT DEPLOYMENT	01-12-2007
60/947,317 ENDOLOG.081PR	GRAFT WITH ELECTRICAL SURFACE CHARGES	06-29-2007
60/981,869 ENDOLOG.085PR	STENT	10-23-2007

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60/955,302 ENDOLOG.087PR	APPARATUS AND METHOD FOR RAPID RELEASE OF THERAPEUTIC AGENT INTO ANIMAL TISSUE	08-10-2007
60/987261 ENDOLOG.087PR2	APPARATUS AND METHOD FOR RAPID RELEASE OF THERAPEUTIC AGENT INTO ANIMAL TISSUE	11-12-2007
60/012356 ENDOLOG.087PR3	APPARATUS AND METHOD FOR RAPID RELEASE OF THERAPEUTIC AGENT INTO ANIMAL TISSUE	12-07-2007
60/987268 ENDOLOG.091PR	METHOD AND AGENT FOR IN-SITU STABILIZATION OF VASCULAR TISSUE	11-12-2007
61/012579 ENDOLOG.092PR	GRAFT WITH THERAPEUTIC AGENT	12-10-2007
61/030913 ENDOLOG.096PR	DESIGN AND METHOD OF PLACEMENT OF AN AORTIC GRAFT	02-22-2008
11/189,101 ENDOLOG.21CP6C2	BIFURCATION GRAFT DEPOLYMENT CATHETER	07-25-2005
11/417,926 ENDOLOG.21CP7C2	IMPLANTABLE VASCULAR GRAFT	05-03-2006
11/764,715 ENDOLOG.21CP7CC	IMPLANTABLE VASCULAR GRAFT	06-18-2007
10/690,227 ENDOLOG.23DV1C1	SINGLE PUNCTURE BIFURCATION GRAFT DEPLOYMENT SYSTEM	10-21-2003
11/214,427 ENDOLOG.4C3C1	BIFURCATED VASCULAR GRAFT AND METHOD AND APPARATUS FOR DEPOLYING SAME	08-29-2005

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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